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PROPOSED ACTION ON REGULATIONS

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SUMMARY OF REGULATORY ACTIONS

The *California Regulatory Notice Register* is an official state publication of the Office of Administrative Law containing notices of proposed regulatory actions by state regulatory agencies to adopt, amend or repeal regulations contained in the California Code of Regulations. The effective period of a notice of proposed regulatory action by a state agency in the *California Regulatory Notice Register* shall not exceed one year [Government Code § 11346.4(b)]. It is suggested, therefore, that issues of the *California Regulatory Notice Register* be retained for a minimum of 18 months.

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PC Section 5054 provides that commencing July 1, 2005, the supervision, management and control of the state prisons, and the responsibility for the care, custody, treatment, training, discipline, and employment of persons confined therein are vested in the Secretary of the CDCR.

PC Section 5055 provides commencing July 1, 2005, all powers and duties previously granted to and imposed upon the Department of Corrections shall be exercised by the Secretary of the CDCR except where those powers and duties are expressly vested by law in the Board of Parole Hearings.

PC Section 5058 authorizes the Director to prescribe and amend regulations for the administration of prisons.

- This action allows the Department to identify inmates with a history of specific sex offenses, and to limit the inmate's opportunity to escape or to re–offend while in custody.
- This proposed amendments will standardize the application of the "R" suffix custody designation with Penal Code (PC) Section 290, Sex Offender — Registration Requirements.
- This amendment will correlate the Department's regulations for applying an "R" suffix to an inmate's custody, to the PC requirement that sex offenders guilty of specific offenses must register as a sex offender for life.
- Changes for enhanced clarity, including references, are also made to meet departmental standards.

TITLE 17. CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

NOTICE OF PROPOSED REGULATION ADOPTION

California Code of Regulations
Title 17. — Public Health
Division 4 — California Institute For Regenerative Medicine
Chapter 3

Date: May 5, 2006

Deadline for Submission of Written Comment: June 19, 2006 — 5:00 p.m.

Hearing Date: June 19, 2006 — 9:00 a.m.

Subject Matter of Proposed Regulations: Intellectual Property Policy for Non–Profit Organizations.

Sections Affected:

The proposed regulations adopt Chapter 3 and sections 100300, 100301, 100302, 100303, 100304, 100305, 100306, 100307, 100308, 100309 and 100310 of Title 17 of the California Code of Regulations.

Authority: Article XXXV of the California Constitution and Health and Safety Code section 125290.40, subdivision (j).

Reference: Section 125290.30, Health and Safety Code.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The California Institute for Regenerative Medicine ("Institute" or "CIRM") was established in early 2005 with the passage of Proposition 71 (the "Act"), the California Stem Cell Research and Cures Initiative. The statewide ballot measure, which provides $3 billion in funding for stem cell research and dedicated facilities at California universities and research institutions, was approved by California voters on November 2, 2004, called for the establishment of a new state agency to make grants and provide loans for stem cell research, research facilities and other vital research opportunities.

The Independent Citizens' Oversight Committee ("ICOC") is the 29–member governing board for the Institute. The ICOC members are public officials, appointed on the basis of their experience earned in California's leading public universities, non–profit academic and research institutions, patient advocacy groups and the biotechnology industry.

The proposed regulations comprise the first of two CIRM intellectual property policies; a second CIRM intellectual property policy will be written to regulate intellectual property that may arise from CIRM funding of for–profit organizations. These regulations are designed to meet the dual goals of academic openness and the need to bring scientific advances to the public via commercialization. A primary objective of the proposed regulations is to promote sharing of all types of intellectual property created as a consequence of CIRM funding for use in research conducted by both academic and commercial research and development organizations. Through the sharing of CIRM–funded data, knowledge, biomedical materials and patented inventions, CIRM strives to promote the general advancement of stem cell research and regenerative medicine. Another objective of the proposed regulations is to facilitate the commercialization of CIRM–funded discoveries without impeding the progress of stem cell research. To facilitate the translation of scientific discoveries to medical therapies, these regulations recognize the importance of transferring research results in the public interest through effective communication and collaboration with commercial entities with appropriate expertise, resources and capacity. Finally, the regu-

lations aim to provide a financial benefit to the State of California through revenue sharing in the event that CIRM–funded discoveries lead to valuable diagnostics and/or medical therapies.

The core principles of the CIRM intellectual property regulations for non–profit organizations are as follows:

1. Ownership: CIRM grantee non–profit organizations will own intellectual property that arises from CIRM–funded research activities.
2. Broad Sharing: Intellectual property, including but not limited to data, knowledge, scientific articles, biomedical materials and patented inventions, that are made in the performance of CIRM–funded research will be shared broadly and promptly with the scientific community. This CIRM sharing policy is structured to extend the sharing of CIRM–funded intellectual property beyond practices commonly in use by the scientific community in 2006.
3. Research Exemption: Patented inventions that are made in the performance of CIRM–funded research are to be made freely available for research purposes in California research institutions.
4. Licensing: For patented inventions that are made in the performance of CIRM–funded research, grantee organizations are expected to negotiate non–exclusive licensing agreements where possible except in those circumstances when exclusivity is required to encourage the successful commercial development of the invention into products and services that can benefit the public. In addition, CIRM has established licensing policies regarding access to resultant therapies and revenue–sharing.
5. March–in rights: Like other funding agencies, CIRM maintains a licensing provision referred to as march–in rights, the purpose of which is to prevent the underutilization of CIRM–funded inventions.

Specifically, the proposed regulations apply to recipients of CIRM grants and establish invention reporting rules, address discovery publication requirements, require sharing of biomedical materials, address patent costs and reporting of patent applications, establish rules regarding granting of exclusive and non–exclusive licenses for patented inventions, create a research exemption for patented inventions for California research institutions, require revenue sharing with the state of California under certain circumstances, require cooperation with the CIRM in press releases referring to CIRM–funded research, and describe the circumstances for march–in rights.

Technical, Theoretical or Empirical Studies, Reports or Documents:

There are many sources that provide helpful information about the administration of CIRM–supported grants or that are relevant to the regulations. Below is a compendium of websites that contains information and useful reports relating to intellectual property, data and materials sharing, and licensing trends. Some components of the proposed regulations were developed using guidelines and regulations contained in these documents:

A. General Interest Sites:

CIRM — http://www.cirm.ca.gov/
NAS — http://www.nas.edu/
NIH — http://www.nih.gov

B. Reports:

Data and biomedical materials sharing:

- 1999 Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources

  http//ott.od.nih.gov/pdfs/64FR72090.pdf

- 2003 Sharing Publication–Related Data and Materials

  http://www.nap.edu/catalog/10613.html

- 2004 A Patent System for the 21st Century

  http://www.nap.edu/catalog/10976.html

- 2005 Considerations in Developing an Intellectual Property Model for Research Grants Awarded by the California Institute for Regenerative Medicine
- 2005 Policy Framework for Intellectual Property Derived from Stem Cell Research in California

  http://www.ccst.us/ccst/subs/IP/IP%20Interim.pdf

- 2005 Implementation of Proposition 71: Options for Handling Intellectual Property Associated with Stem Cell Research Grants

  http://democrats.sen.ca.gov/articlefiles/455110.31.05%20IP%20hearing%20transcript.doc

- 2005 Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation and Public Health

  http://www.nap.edu/catalog/11487.html

- 2006 Policy Framework for Intellectual Property Derived from State Funded Research

  http://www.ccst/us/ccst/pubs/ip/ipfinal.pdf

General patent information:

- http://web.mit.edu/tlo/www/patentbars.html
- http://www.uspto.gov/

Licensing trends:

- 2002 Association for University Technology Managers: Licensing Survey

  http://www.autm.net/events/File/Surveys/02_Abridged_Survey.pdf
- 2003 Association for University Technology Managers: Annual Report

  http://www.autm.net/events/File/Surveys/03_Abridged_Survey.pdf

Alternative intellectual property models:

- 2003 Independent Evaluation of the International AIDS Vaccine Initiative

  http://www.iavi.org/file.cfm?fid=416
- 2004 International AIDS Vaccine Initiative Annual Report

  http://www.iavi.org/viewpage.cfm?aid=48

Biotechnology

- 2004 California's Biomedical Industry

  http://chi.org/brandomatic/othermedia/chi/biomed.pdf

C. Public Input

Public input received at nine public meetings conducted by the ICOC and Intellectual Property Task Force Subcommittee on: February 3, 2005; July 12, 2005; August 5, 2005; October 25, 2005; November 2, 2005; November 22, 2005; December 5, 2005; January 23, 2006; and February 10, 2006.

Copies of the documents referenced above may be found at the internet site listed. In addition, these documents are also available at the offices of CIRM located at 210 King Street, San Francisco, California, 94107. Transcripts and meeting minutes of the meetings referenced in Section "C" are available on CIRM's website, www.cirm.ca.gov under the "Meetings Transcripts" link.

Submittal of Comments:

Any interested party may present comments in writing about the proposed action to the agency contact person named in this notice. Written comments must be received no later than 5:00 p.m. on June 19, 2006. Comments regarding this proposed action may also be transmitted via e–mail to nonprofitipregs@cirm.ca.gov or by facsimile transmission to (415) 396–9141.

A public hearing has been scheduled for the time and place stated below to receive **oral comments** regarding the proposed regulatory action.

Date: **June 19, 2006**

Time: 9:00 a.m. to noon.

Place: California Institute for Regenerative Medicine
250 King Street
San Francisco, CA 94117

A CIRM representative will preside at the hearing. Persons who wish to speak will be asked to register before the hearing. The registration of speakers will be conducted at the location of the hearing from 8:30 a.m. to 9:00 a.m. Any other person who wishes to speak at the hearing will be afforded the opportunity to do so after the registered persons have been heard. If the number of registered persons in attendance warrants, the hearing officer may limit the time for each presentation in order to allow everyone wishing to speak the opportunity to be heard. Oral comments presented at a hearing carry no more weight than written comments.

Effect on Small Business:

CIRM has determined that the proposed regulatory action has no impact on small businesses. The regulations implement conditions on awarding grants for stem cell research. This research is conducted almost exclusively by large public and private non–profit institutions, as well as large for–profit institutions. As such, the regulations are not expected to adversely impact small business as defined in Government Code section 11342.610.

Impact on Local Agencies or School Districts:

CIRM has determined that the proposed regulatory action does not impose a mandate on local agencies or school districts, nor does it require reimbursement by the state pursuant to Part 7 (commencing with section 17500) of Division 4 of the Government Code because the regulatory action does not constitute a "new program or higher level of service of an existing program" within the meaning of section 6 of Article XIII of the California Constitution. CIRM has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action.

Costs or Savings to State Agencies:

CIRM has determined that no savings or increased costs to any agency will result from the proposed regulatory action.

Effect on Federal Funding to the State:

CIRM has determined that no costs or savings in federal funding to the state will result from the proposed regulatory actions.

Effect on Housing Costs:

CIRM has made an initial determination that the proposed actions will have no effect on housing costs.

Significant Statewide Adverse Economic Impact Directly Affecting Businesses:

CIRM has made an initial determination that adoption of this regulation will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California Businesses to compete with businesses in other states.

Cost Impacts on Representative Private Persons or Businesses:

CIRM has made an initial determination that the adoption of this regulation will not have a significant cost impact on representative private persons or businesses. The CIRM is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Impact on the Creation, Elimination, or Expansion of Jobs:

CIRM has determined it is unlikely the proposed regulatory action will impact the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California.

Consideration of Alternatives:

CIRM must determine that no reasonable alternatives considered by the agency, or that have otherwise been identified and brought to the attention of the agency, would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons or businesses than the regulatory action.

Availability of Statement of Reasons and Text of Proposed Regulations:

CIRM has prepared an Initial Statement of Reasons, and has available the express terms of the proposed action, all of the information upon which the proposal is based, and a rulemaking file. A copy of the Initial Statement of Reasons and the proposed text of the regulation may be obtained from the agency contact person named in this notice. The information upon which CIRM relied in preparing this proposal and the rulemaking file are available for review at the address specified below.

Availability of Changed or Modified Text:

After the close of the comment period, CIRM may make the regulation permanent if it remains substantially the same as described in the Policy Statement Overview. If CIRM does make changes to the regulation, the modified text will be made available for at least 15 days prior to adoption. Requests for the modified text should be addressed to the agency contact person named in this notice. CIRM will accept written comments on any changes for 15 days after the modified text is made available.

Agency Contact:

Written comments about the proposed regulatory action; requests for a copy of the Initial Statements of Reasons, the proposed text of the regulation, and a public hearing; and inquiries regarding the rulemaking file may be directed to:

C. Scott Tocher, Interim Counsel
California Institute For Regenerative Medicine
210 King Street
San Francisco, CA 94107
(415) 396–9100

Questions on the substance of the proposed regulatory action may be directed to:

Mary E. Maxon, Ph. D., Deputy Vice Chair
California Institute For Regenerative Medicine
(415) 396–9100

The Notice of Proposed Regulatory Adoption, the Initial Statement of Reasons and any attachments, and the proposed text of the regulations are also available on CIRM's website, www.cirm.ca.gov.

Availability of Final Statement of Reasons:

Following its preparation, a copy of the Final Statement of Reasons mandated by Government Code section 11346.9, subdivision (a), may be obtained from the contact person named above. In addition, the Final Statement of Reasons will be posted on CIRM's webpage and accessed at www.cirm.ca.gov.

GENERAL PUBLIC INTEREST

TITLE 2. DEPARTMENT OF FAIR EMPLOYMENT AND HOUSING

NOTICE IS HEREBY GIVEN that the prospective contractors listed below have been required to submit a Nondiscrimination Program (NDP) or a California Employer Identification Report (CEIR) to the Department of Fair Employment and Housing, in accordance with the provisions of Government Code Section 12990. No such program or (CEIR) has been submitted and the prospective contractors are ineligible to enter into State contracts. The prospective contractor's signature on